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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER |
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SHARAREH, SHAHNAM J

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,951

Applicant(s)

WHALEN ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-37 are pending.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "the viscosity of said composition" in claims 1 and 2 renders the claims indefinite, because it is not clear to which viscosity is applicant referring? Is this the viscosity of the composition before the polymer precipitate is formed, or is this the viscosity of the composition after the polymer precipitate is formed? The metes and

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bounds of the claim, accordingly, one of ordinary skill in the art would not be able to reasonably apprise the scope of the invention.

Claim 2 recites the limitation "the complete composition" in line 19. There is insufficient antecedent basis for this limitation in the claim. It is not clear what is considered the complete composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent 5,580,568 (IDS, Paper No. 4); claims 1-43 of U.S. Patent No. 5,695,480 (IDS, Paper No. 4); claims 1-15 of U.S. Patent No. 5,851,508 (IDS, Paper No. 4); claims 1-15 of U.S. Patent 5,667,767 (IDS, Paper No. 4); claims 1-17 of U.S. Patent No. 6,051,607; claims 1-21 of U.S. Patent No. 6,214,315, claims 1-20 of US Patent 6,454,738, and claims 1-15 of US Patent 6,531,111. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patented claims and the instant

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pending claims are directed to compositions comprising a biocompatible polymer, a biocompatible contrast agent and a biocompatible solvent. Accordingly, the pending claims are obvious variants of the patented claims.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-13, 15-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Evans et al et al US Patent 5,695,480 (Evans) (IDS, Paper No.4).

The instant claims are directed to compositions comprising a biocompatible polymer such as ethylene vinyl alcohol copolymer, a biocompatible contrast agent such as tantalum, and a biocompatible solvent such as dimethyl sulfoxide (DMSO).

Applicant is informed that where a composition is claimed in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function or characteristic is not explicitly disclosed by the reference the Examiner can make a rejection under both 35 U.S.C 102 and 103, expressed as 102/103 rejection (see MPEP 2112).

Evans discloses compositions comprising ethylene vinyl alcohol copolymer in concentrations of 8% weight, tantalum in concentrations of 30% weight and DMSO in amounts of 100 ml (52-87.5% weight) (see col 10, lines 15-67; col 11, lines 54-67).

Further, Evans' compositions have a viscosity of less than 60 centipoise at 20° C (see col 5, lines 37-43). Evans also discloses administration of his compositions employing a microballoon cathater. (col 4, lines 1-20). Accordingly, Evans anticipates the limitations of the instant claims.

Although Evans does not specifically recite the instantly claimed viscosity of 150 cSt at 40 ° C or migration distance, Examiner takes the position that compositions disclosed by Evans inherently possess the same viscosity and migration distance as the instantly claimed invention, because Evans' compositions comprise similar component used in overlapping range of concentrations as those claimed in the instant application.

Moreover, "to serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Accordingly, to clarify the asserted inherent characteristics, Applicant's attention is drawn to the definition of "kinematic viscosity" and "dynamic viscosity" set forth in attached Stenesh, Dictionary of biochemistry and Molecular Biology, 2nd edition, 1989.

As described in Stenesh, kinematic viscosity (measured in the unit of "stoke" or "centistokes=cSt") is the dynamic viscosity (measured in the unit of "poise" or "centipoise") of a liquid formulation divided by its density (see page 262). Thus, since the density of any given composition is a constant measure equal to its mass (weight)

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divided by the unit volume of the composition, kinematic viscosity of any composition is directly correlated with its Dynamic Viscosity.

In the instant case, the compositions of the pending claims are defined in term of "kinematic viscosity," however, the compositions of Evans are defined in terms of their "dynamic viscosity" (see col 9, lines 30-31). Accordingly, as Evans compositions comprise the same components as the instantly claimed components, and further they are made with the same amount of each given component as the instantly claimed compositions; it is Examiner's position that the "dynamic viscosity" and the "density" of Evan's compositions are within the same range as the "dynamic viscosity" and the "density" of the instantly claimed compositions. Subsequently, Evans' compositions possess the same "kinematic viscosity" as the instantly claimed compositions, because a measurement of "kinematic viscosity", as set forth above in Stenesh, is directly correlated to the "dynamic viscosity" of Evans composition divided by its "density."

In alternative, where Evans' compositions do not possess the same viscosity as instantly claimed, absence of showing the criticality, it would have been *prima facie* obvious to optimize the viscosity range of Evans' compositions by routine experimentation (see 2144.05 II). The ordinary skill in the art would have been motivated to optimize the viscosity of the Evans' final formulation, because he would have had a reasonable expectation of success in achieving the safest clinical outcome and avoiding transvenous passage when using Evans' compositions as an embolizing agent.

4. Claims 1-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Greff et al US Patent 5,667,767 (Greff I) (IDS, Paper No.4).

Greff I discloses embolizing compositions comprising ethylene vinyl alcohol copolymers at a concentration of 5.8 and 6.8% weight, tantalum at concentrations of 10% weight, and DMSO at concentrations of about 52% to about 87.5% weight (see examples 3-4, col 8-9; and col 10, lines 13, and 20-21; col 10, lines 7-26). Greff I also discloses the use of a water soluble contrast agent such as metrizamide at concentrations of 38.5% weight (see col 9, lines 3-7). Greff I administers his compositions at the site of interest via a cathater (example 5). Accordingly, using the same analogy as above, Greff I anticipates the instant claims.

In alternative, where Greff's compositions do not possess the same viscosity or the migration distance as instantly claimed, absence of showing the criticality, it would have been *prima facie* obvious to optimize the viscosity range of Greff's composition by routine experimentation and obtain the optimal range for the best clinical outcome (see 2144.05 II). The ordinary skill in the art would have been motivated to optimize the viscosity of such compositions, because he would have had a reasonable expectation of success in achieving the safest clinical outcome while avoiding transvenous passage when using Greff's compositions.

5. Claims 1-6, 9-10, 14-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Taki et al (AJNR 11: 163-168, January/February 1990) (Taki) (IDS, Paper No. 4).

The instant claims are directed to compositions comprising a biocompatible polymer such as ethylene vinyl alcohol copolymer, a biocompatible contrast agent, and a biocompatible solvent such as dimethyl sulfoxide (DMSO).

Taki discloses embolizing compositions comprising ethylene vinyl alcohol copolymers at a concentration of 5% weight, metrizamide at concentrations of 35% weight, and DMSO at concentrations of about 60% weight (see abstract and Material and Methods in page 163; also page 164, Table I). Although Taki does not explicitly disclose the instantly claimed viscosity of 150 cSt at 40 ° C or the migration distance, using the same analogy as discussed above, Examiner takes the position that compositions disclosed by Taki inherently possess the same viscosity and migration distance as the instantly claimed invention, because Taki's compositions comprising similar component and similar range of concentrations as those claimed in the instant application.

Similar to the reasoning set forth above, in alternative, where Taki's compositions do not possess the same viscosity as instantly claimed, absence of showing the criticality, it would have been *prima facie* obvious to optimize the viscosity range of Taki's composition by routine experimentation (see MPEP 2144.05 II). One of ordinary skill in the art would have been motivated to do such modifications, because he would have had a reasonable expectation to succeed in achieving the optimal range of viscosity for the most effective clinical outcome.

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6. Claims 1-6, 9-17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Greff et al US Patent 6,214,315 B1 (Greff II) (IDS, Paper No. 4).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Greff II discloses compositions comprising ethylene vinyl alcohol copolymers at a concentration of about 5% weight, tantalum at concentrations of 14% weight, and DMSO at concentrations of about 74% weight and Iridium powder at concentrations of about 6% weight (see examples 1, col 12, lines 62-66). Greff II also discloses methods of administering his compositions using a microballoon cathater. Accordingly, using the same analogy as above, Greff II anticipates the limitations of the instant claims.

In alternative, where Greff's compositions do not possess the same viscosity or the migration distance as instantly claimed, for the same reasons set forth above, it would have been *prima facie* obvious to optimize the viscosity range of Greff's composition by routine experimentation, thus obtaining the optimal range of viscosity for the safest and most effective clinical outcome.

Conclusion

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No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
March 23, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200